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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/550,181	09/21/2005	Shailesh Bhamare	11336.1004USWO	1149	
52835	7590 02/07/200	EXAM	EXAMINER		
HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902			SASAN, A	SASAN, ARADHANA	
MINNEAPOLIS, MN 55402-0902			ART UNIT	PAPER NUMBER	
	•	•	1615		
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			MAIL DATE	DELIVERY MODE	
			02/07/2008	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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		Application No.	Applicant(s)
		10/550,181	BHAMARE ET AL.
	Office Action Summary	Examiner	Art Unit
		Aradhana Sasan	1615
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the	correspondence address
A SH WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. O period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDO	ON. timely filed om the mailing date of this communication. NED (35 U.S.C. § 133).
Status		·	
	Responsive to communication(s) filed on <u>21 Sec</u> This action is FINAL . 2b) This Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, p	
Dispositi	ion of Claims	•	
5) 6) 7)	Claim(s) 1-22 is/are pending in the application. 4a) Of the above claim(s) is/are withdray Claim(s) is/are allowed. Claim(s) is/are rejected. Claim(s) is/are objected to. Claim(s) 1-22 are subject to restriction and/or expressions.	vn from consideration.	
Applicati	ion Papers		
10)	The specification is objected to by the Examine The drawing(s) filed onis/ are: a) access Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction The oath or declaration is objected to by the Example 1.	epted or b) objected to by the drawing(s) be held in abeyance. So ion is required if the drawing(s) is a	See 37 CFR 1.85(a). objected to. See 37 CFR 1.121(d).
Priority (under 35 U.S.C. § 119		
a)	Acknowledgment is made of a claim for foreign All b) Some * c) None of: Certified copies of the priority documents Certified copies of the priority documents Copies of the certified copies of the prioricy application from the International Bureau See the attached detailed Office action for a list of	s have been received. s have been received in Applicative documents have been received in Received in PCT Rule 17.2(a)).	ation No ived in this National Stage
Attachmen		_	
2) Notic 3) Infon	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date	4) Interview Summa Paper No(s)/Mail 5) Notice of Informa 6) Other:	

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-18, drawn to a stabilized pharmaceutical solid composition comprising of an ACE inhibitor and meglumine.

Group II, claim(s) 19-22, drawn to a process of preparation of a stable formulation of ACE-inhibitor.

As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT); "the international application shall relate to one invention only or to a group of inventions." Moreover, as stated in Rule 13.2 PCT, Unity of Invention is satisfied "where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art so linked as to form a single general inventive concept." The examiner respectfully submits that, as presented, the instant claim(s) 1-18, drawn to a stabilized pharmaceutical solid composition comprising

of an ACE inhibitor and meglumine do not present a contribution over the prior art. As disclosed in US 20020039594, a composition with ACE inhibitors and meglumine is taught by the prior art (Page 45, claims 45 and 57). As a result, as currently presented, instant claims 1-18 do not share a special technical feature with the instant process claims 19-22 and, as such, unity between the above Groups I – II is broken.

2. The inventions listed as Groups I – II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of Group I is a stabilized pharmaceutical solid composition comprising of an ACE inhibitor and meglumine. The technical feature of Group II is a process of preparation of a stable formulation of ACE-inhibitor. Group I is drawn to a product whereas group II is drawn to a process of preparing a product. As such, Group I and Group II do not share the same special technical feature. Therefore, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept.

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL P. WOODWARD SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600